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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,015	04/10/2001	Nancy J. Woolf	NJW-1	9668

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,015	WOOLF ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 24 February 2004 has been received and entered in full.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

3. The Rejection of claims **1** and **4** under 35 U.S.C. §112 ¶2 for the reasons as set forth at pp. 9-10 ¶26-28 of the previous Office Action (25 August 2003) are hereby *withdrawn* in view of Applicant's amendments (24 February 2004).

4. The Objection to claim **9** for the reasons as set forth at pp. 3 ¶8 of the previous Office Action (25 August 2003) are hereby *withdrawn* in view of Applicant's amendments (24 February 2004).

Maintained Objections And/Or Rejections

5. Claims **1-9** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons as set forth at pp. 3-7 ¶9-19 of the previous Office Action (25 August 2003).

6. Applicant traverses this rejection on the following grounds: **(a)** neither a narrow genus nor the specification of an antagonist is required for a disclosure to be enabling, **(b)** the Specification only contains prophetic examples, **(c)** Applicants respectfully submit that they have taught a process by which the chemical agents at issue may be clearly identified, **(d)** the prior art discloses a multitude of methods for diagnosing the treatment of Alzheimer's disease (incorporation of references), **(e)** a limited amount of experimentation required is routine (pp. 13-15), **(f)** not all the "*Wands*" factors have been considered in the enablement rejection, and **(g)** Applicant provides a review of the literature to support their suggestion for invention (pp. 15-20).

7. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

8. On "**(a)**", Applicant has admitted on the record that they do not in fact posses the "antagonist which inhibit phosphorylation of MAP-2" which is required to practice the invention as claimed. Therefore the instant claims as a whole represent an invitation to experiment. While antagonists which inhibit phosphorylation of MAP-2 may constitute a fecund ground for investigation, the CAFC ruled in *Genentech Inc. v. Novo Nordisk A/S* (CA FC) **42 USPQ2d 1001** (1997) that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Citing *Brenner v. Manson,* **383 U.S. 519, 536, 148 USPQ 689, 696** (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore the CFAC stated that tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic

claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in the instant specification with respect to the any antagonists which inhibit phosphorylation of MAP-2 which in turns has therapeutic activity for Alzheimer's disease.

9. On "**(b)**", Applicant has admitted on the record that the Specification does not contain any working examples, only suggestions on how to accomplish the invention. As discussed in the previous Office Action (25 August 2003) this suggestion includes an enormous quantity of experimentation necessary to identify all the applicable antagonists which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutics, the lack of direction/guidance presented in the specification regarding synthesizing, screening, and evaluating all applicable antagonists which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutics, the absence of working examples directed to known antagonists which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutics, the complex nature of the invention, the unpredictability of the effects of antagonists which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutics on cells and/or patients, and the breadth of the claims which fail to recite limitations for what constitutes an applicable antagonists which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutics, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

10. On "**(c)**", as noted above this statement constitutes an invitation to experiment.

11. On "**(d)**", this statement is not relevant as the instant claims are drawn to a therapeutic method. Further none of the prior art nor the disclosure of the Specification teaches an antagonist which inhibit phosphorylation of MAP-2 which may be Alzheimer's disease therapeutic.

12. On "**(e)**", as noted above this statement constitutes an invitation to experiment.

13. On "**(f)**", see previous Office Action (25 August 2003).

14. On "**(g)**", the Specification and the prior art offer no examples of compounds, antibodies, nucleic acids, proteins, or other "antagonists" are provided by the instant Specification as filed or the prior art that meet the limitations of claim 1 and would be useful for treating Alzheimer's disease. While putting forth the proposition of using a neurotransmitter receptor antagonist for treating Alzheimer's disease, no evidence is present in the instant Specification or the prior art as to guide the skilled artisan to identify or use the desired neurotransmitter receptor antagonist as a therapeutic. What remains is an invitation to experiment, first to determine which neurotransmitter antagonist satisfies the limitations of claim 1, and then determine its role, and finally the course of therapy that would have a salubrious outcome {see MPEP §2164.01(a)}.

15. Furthermore MPEP §2145 clearly states that attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection (MPEP § 2129 and §2144.03). Furthermore, the arguments of counsel cannot take the place of evidence in the record. In the instant case the Applicant is asserting that XYZ while no data, information, or teaching supports XYZ in the instant Specification {see *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and

not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") and MPEP § 716.01(c)}.

16. Thus in the absence of guidance and working examples, the skilled artisan is confronted with an undue burden of experimentation in an unpredictable and undeveloped art to practice the invention as claimed.

17. Claims **1-9** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons as set forth at pp. 7-9 ¶20-25 of the previous Office Action (25 August 2003).

18. Applicant traverses this rejection on the following grounds: **(a)** "Applicants respectfully submit they must show possession of the process of the invention, and not possession of a compound, as a compound is not being claimed" (pp. 22 Response filed 24 February 2004).

19. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

20. On "**(a)**", this it taken to be an admission on the record that Applicant does not in fact posses an "antagonist which inhibit phosphorylation of MAP-2". Therefore, Applicant can on be in material possession of any methods (processes) of manufacture or use thereof.

21. The claims require an "antagonist which inhibit phosphorylation of MAP-2". The claims do not require that the antagonist to possess any particular conserved structure, or other

distinguishing feature. Thus, the claims are drawn to a genus of agents that is defined by desired activity.

22. Furthermore the art recognizes that "antagonist" can pertain to chemical entities, pharmaceutical compositions, proteins, peptides, non-peptide compounds, animal tissue extracts, nucleic acids, antisense molecules, peptidomimetic, transformed cells, radiation, antibodies, antibody fragments, cyclic peptides, agonists, antagonists, inhibitors, enhancers, vegetable extracts, cell extracts, synthetic agents, biologically derived substances as well as proteinaceous substances, known, and unknown compounds.

23. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a recitation of a desired activity. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

24. Applicant states: "Applicants respectfully submit that they have taught a process by which the chemical agents at issue may be clearly identified" (pp. 12 Response filed 26 February 2004). Thereby admitting on the record that the "antagonist" is not known and must be identified, characterized, and tested in treatments of Alzheimer's disease.

25. But to satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since specification did not indicate that compounds are available in public depository, the claimed treatment method cannot be practiced without compound. Thus the inventors cannot be said to have "possessed" claimed invention without knowing of a compound or method certain to produce compound. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties.

26. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Summary

27. No claims are allowed.

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
April 9, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER